REMARKS/ARGUMENTS

In the specification, pages 4-6 have been amended to provide a period (.) at the end of each sentence as needed.

Claims 34 and 36 have been amended to more particularly define the strain of Streptococcus to which an immune response is obtained with the claimed method and vaccine. Claim 36 also has been amended to delete language meant to define the animal being treated by the claimed method. This amendment does not narrow the scope of the claim.

Applicant acknowledges the mistake pointed out by the Examiner on page 9 of the Office Action in regards to the claim of priority to co-pending application 09/471,255. The mistaken claim to priority was made in the previous response to Office Action without deceptive intent.

I. Rejection of Claims 18, 25 and 34 Under 35 USC § 112 (Enablement)

Claims 18, 25 and 34 are rejected under 35 USC § 112, first paragraph. The Examiner states that the specification does not provide sufficient guidance to enable the person of skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims.

This rejection is respectfully traversed as follows.

The claimed chimeric polypeptide, SEQ ID NO. 332 (also identified as VP 94 in the specification), is composed of two immunoprotective polypeptides derived from *S. pneumoniae*, NEW 60 and NEW 56, which are separated by a two amino acid linker. Each of the *S. pneumoniae* peptides that comprise SEQ ID NO. 332 is a fragment of *S. pneumoniae* protein BVH-11 or BVH-3 and each fragment is derived from a region of BVH-11 or BVH-3 shown to confer immunogenicity.

Each of the fragments has been shown to provide protection against *S. pneumoniae in vivo* when administered as a vaccine. The data provided in the enclosed declaration of Dr. Martin show that the chimeric peptide, SEQ ID NO. 332 is also immunoprotective and is at least as immunoprotective as the two fragments from which it is derived.

The specification provides information concerning the general location of protective epitopes in the BVH-11 and BVH-3 proteins, *i.e.*, cell surface exposed regions of the proteins which are shown in Figures 15 and 16, and provides examples of several peptide fragments of BVH-11 and BVH-3 within or encompassing the cell surface exposed regions. It is specifically taught in the specification that these fragments may be used to generate chimeric peptides that have immunogenic properties.

The specification provides sequence information of BVH-11 and BVH-3, as well as several fragments of these proteins and several chimeric polypeptides composed of BVH-11 and/or BVH-3 peptide fragments. Among the chimeric peptides disclosed in the specification are several chimeras which share at least about 85% sequence similarity to SEQ ID NO:332, and which are composed of two fragments derived from the cell surface exposed regions of BVH-11 and/or BVH-3, *e.g.*, NEW17, NEW28, VP109, VP112 and VP113. These polypeptides, which are described in Tables H or G of the specification, and SEQ ID NO. 332 were generated by Dr. Denis Martin, one of the co-inventors, and tested *in vivo* for immunoprotective properties. The results are reported in Dr. Martin's declaration, which is enclosed herewith and summarized in the Table below.

Protection mediated chimeric gene products NEW17, New28, VP94, VP112 and VP113 in experimental pneumonia

Experiment	Immunogen	Alive: Dead	Days to death post-infection
1	None	0 : 8	2, 2, 2, 2, 2, 3, 2, 2
	NEW 17	6 : 2	>14, >14, >14, >14, >14, 7, 6, >14
2	None	1 : 7	4, 4, 4, >14, 4, 5, 4, 4
	New 28	8 : 0	8 X >14
3	None	0 : 8	4, 3, 4, 4, 4, 4, 5, 3
	VP 94	8 : 0	8 X >14
4	None	0 : 6	5, 5, 5, 4, 5, 4
	VP 109	6 : 0	6 X >14
5	None	0 : 8	4, 4, 1, 4, 5, 5, 5, 5
	VP 112	5 : 3	>14, 6, 5, >14, 6, >14, >14, >14
	VP 113	6 : 2	>14, >14, >14, 5, >14, >14, >14, 10

As can be seen, all six chimeric peptides provide immunoprotection *in vivo* from challenge with *S. pneumoniae*. Significantly, each of the chimeras provides a protective immune response comparable to or better than that observed when the individual peptide fragments which make up the chimera is used to immunize animals (Tables 14 and 21 of the specification).

The results obtained with these six chimeras demonstrate that the SEQ ID NO. 332 is immunoprotective *in vivo* and the SEQ ID NO. 332 peptide can withstand up to 15% amino acid

alteration and retain its immunoprotective property. Applicants tested five different variations of SEQ ID NO. 332 , each of which exhibits at least 85% sequence similarity to SEQ ID NO. 332, and in all five cases, the resulting chimeric peptide exhibited immunoprotection *in vivo*. These data demonstrate that the skilled practitioner can use the information provided in the specification to generate chimeric peptides that are expected to have immunogenic properties.

The skilled practitioner is knowledgeable in the field of protein chemistry and can readily vary the amino acid sequence based upon the teachings of the specification, and would recognize which types of modifications are most likely to be successful based on the teachings of the specification.

On the basis of the teachings of the specification, the skilled practitioner would recognize that there are two immunogenic portions of the claimed peptides, one on either side of the linker. The data in table 2 of the declaration demonstrate that variations to one immunogeic portion of SEQ ID NO. 332 are likely to have no effect on the immunogenicity of the peptide overall.

Thus, the specification clearly provides guidance for varying the sequence of SEQ ID NO. 332 while still maintaining immunogenicity of the peptide to enable the generation of a genus of peptides commensurate in scope with the claims.

It is not required that every species encompassed by a genus must be operative. It is only required that the skilled practitioner be able to determine which embodiments would be operative or inoperative with no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984). It is submitted that the skilled practitioner can determine which chimeras encompassed by the claims are operative and which are not without undue experimentation, particularly since such tests are routine in the art (see Dr. Martin's declaration). Moreover, the specification clearly shows which types of chimeras within

the scope of the claims can be expected to be immunogenic, and the data in Dr. Martin's declaration demonstrate a success rate of 100% (5/5).

Accordingly, it is respectfully submitted that the rejection of claims 18, 25 and 34 under 35 USC § 112, first paragraph is respectiully traversed.

II. Rejection of Claim 36 Under 35 USC § 112

It is respectfully submitted that the amendment to claim 36renders this ground of rejection moot.

III. Rejection of Claim s 18, 25 and 34-36 Under 35 USC § 112 (Enablement)

Claims 18, 25 and 34 are rejected under 35 USC § 112, first paragraph. The Examiner asserts that the specification does not provide sufficient guidance to enable the skilled practitioner to make and use the claimed peptides, vaccines and methods of treating and preventing Streptococcal infections.

This rejection is traversed as follows.

The claims have been amended to recite that the vaccines and methods treat or prevent *S. pneumoniae* infections, and the enclosed declaration bears that out. Dr. Martin demonstrated that SEQ ID NO. 332 protects animals *in vivo* from challenge with experimental *S. pneumoniae,* and provided five examples of chimeric peptides made by the processes described in the specification which share at least 85% sequence identity with SEQ ID NO. 332 and which are also immunoprotective *in vivo*. As Dr. Martin states in his declaration, it is not undue experimentation to make the chimeras in accordance with the teachings of the specification, nor is it undue experimentation to test the chimeras *in vivo* using routine vaccination and bacterial challenge protocols.

The specification teaches how to make the chimeras, provides examples of animal testing, and provides guidance for the selection of chimeras expected to provide immunoprotection *in vivo*. Further, the declaration shows a 100% success rate with the generation of chimeras that have immunoprotective properties made using the guidance provided by the specification.

Thus one of skill in the art, relying on the teachings of the specification is enabled to make and use the claimed invention.

Accordingly, the rejection of claims 18, 25 and 34-36 under 35 USC § 112, first paragraph is respectfully traversed.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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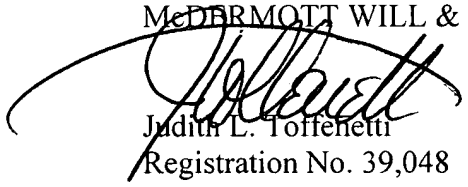

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